

Policy Number: 12

Title: IRB Review of Human Subjects Research - Exempt

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Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that all human subjects research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the exemption categories described in the Federal regulations and complies with UC Irvine's ethical standards.

I. Exempt Eligibility

- A. Research activities involving human subjects may be exempt from the requirement that they receive IRB full or expedited review as per the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA).
 - 1. **Exempt Self-Determination Tool:** Lead Researchers (and Faculty Sponsors as applicable) and Undergraduate Research Opportunities Program ([UROP](#)) students may use the Exempt Self-Determination Tool through the electronic IRB submission and management system to confirm exempt categories 1-4.
 - 2. When using the Exempt Self-Determination Tool, the following exceptions apply;
 - a. Exemptions 2iii, and 3iC. (limited IRB review is required)
 - b. Exempt Categories 5-8
 - c. The research is regulated by the FDA
 - d. The research is supported by the Department of Justice (DOJ)
 - e. The research is supported by the Department of Energy (DOE)
 - f. The research does not involve the following:
 - i. The use or disclosure of UC/UCI records (e.g., medical, student, employment when the [California Information Practices Act \(CIPA\)](#) is applicable)
 - ii. The creation, access to use or disclosure of [UCI protected health information \(PHI\)](#)^{**1}
 - iii. A targeted recruitment of children
 - iv. A targeted recruitment of adults (age 18 or older) who may not be legally/mentally/cognitively competent to consent
 - v. A targeted recruitment of prisoners (may include parolees)
 - vi. A targeted recruitment of American Indian/Alaska Native tribes
 - vii. A targeted recruitment of undocumented people
 - viii. International Research
 - ix. A request for UCI to serve as IRB of Record for non-UCI individuals engaged in human subjects research.
Note: To initiate a request for UCI to serve in this capacity, the LR must have a dual affiliation with the non-UCI entity and IRB review is required to formalize the reliance process.

¹ Use is any sharing, employment, application, utilization, examination, or analysis within the entity. Disclosure is any release, transfer, provision of access to (*including the observation of*), or divulging outside of entity.

- x. A study team member has a Disclosable Financial Interest

3. **IRB Confirmation of Exemption:** Lead Researchers (and Faculty Sponsors as applicable) may receive exempt confirmation by IRB Chairperson, designated IRB subcommittee, or HRP Staff Reviewer using the following mechanism;

- a. An IRB Application for Exemption
 - i. Investigators must submit a completed IRB application to conduct Exempt human subjects research that otherwise does not qualify for UROP review or completion of the Exempt Self-Determination Tool.
 - ii. Exempt confirmation may be granted for no more than three (3) years. A renewal application may be submitted to continue the research.

B. **2018 Common Rule Exempt Categories:** For research that falls under the 2018 Common Rule (i.e., new studies approved on or after January 21, 2019 or for continuing studies approved before January 21, 2019 receiving a new or renewal of a federal award (See Policy # 18)), research may be granted exempt status if all research activities involve procedures listed in one or more of the specific categories under **45 CFR 46.104(d)**:

- 1. **45 CFR 46.104(d)(1):** Research, conducted in **established or commonly accepted educational settings** that specifically involves **normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction**. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2. **45 CFR 46.104(d)(2):** Research that includes only **interactions involving educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures, or observation² of public behavior** (including visual or auditory recording) **if at least one of the following criteria are met:**

- i. The information obtained is recorded by the investigator in such a manner that the **identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects;
- ii. Any **disclosure** of the human subjects' responses outside the research **would not reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;
OR
- iii. The information obtained is recorded by the investigator in such a manner that the **identity of human subjects can readily be ascertained**, directly or through identifiers linked to the subjects, **and an IRB conducts a limited review to make the determination required by 45 CFR 46.111(a)(7)**

Note: For Category 2iii, any disclosure of the human subjects' responses outside the research *would* reasonably place the subjects at risk of criminal or civil liability or be damaging to the

² Children may be included if procedures include educational tests or observation of public behavior only and the researcher does not participate in the activities being observed.

subjects' financial standing, employability, educational advancement, or reputation.

3. **45 CFR 46.104(d)(3i):** Research involving **benign behavioral interventions** in conjunction with the collection of information from an **adult subject** through verbal or written responses (including data entry) **or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:**

- a. The information obtained is recorded by the investigator in such a manner that the **identity of the human subjects cannot readily be ascertained directly** or through identifiers linked to the subjects;
- b. Any **disclosure** of the subjects' responses outside the research **would not reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **OR**
- c. The information obtained is recorded by the investigator in such a manner that the **identity of the human subjects can readily be ascertained**, directly or through identifiers linked to the subject, **and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7)**

Note: For Category 3iC, any disclosure of the human subjects' responses outside the research *would* reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

- ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
- iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. **45 CFR 46.104(d)(4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens**, if at least one of the following criteria is met:

- i. The identifiable private information or identifiable biospecimens are **publicly available**;

Note: Category 4i applies to secondary research use of archives in a public library, for example, or to government or other institutional records where public access is provided on request, or from a commercial entity if the information is provided to members of the public on request or if the only requirement for obtaining the information is paying a user fee, registering or signing in as a visitor to an archive. It would also apply if a

- commercial entity made identifiable biospecimens publicly available to anyone on request or for a fee.
- ii. Information, which may include information about the biospecimens, is recorded by the investigator in such a manner that the **identity of human subjects cannot readily be ascertained** directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - iii. The research involves only information collection and analysis involving the investigator's use of **identifiable** health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); **OR**
Note: Category 4iii is allowable when a UCI healthcare workforce member uses identifiable health information for research purposes and the information obtained for research will not be disclosed outside of the covered entity (i.e., not outside of UCI Health). **IMPORTANT!** Disclosure beyond UCI Health for research purposes does not meet category 4iii and the project should be submitted as Expedited Category 5.
 - iv. The research is **conducted by, or on behalf of, a Federal department or agency** using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
5. **45 CFR 46.104(d)(5): Research and demonstration projects that are conducted or supported by a Federal department or agency**, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
- i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. **45 CFR 46.104(d)(6): Taste and food quality evaluation and consumer acceptance studies:**
 - i. If wholesome foods without additives are consumed; **OR**
 - ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture.
7. **45 CFR 46.104(d)(7): Storage or maintenance for secondary research for which broad consent is required:** Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
Note: UCI will not adopt Category 7. UCI's interpretation of Broad consent is that it is a system-wide program that allows institutions to track via a central system biospecimens and data for which individuals provide their broad consent, or decline, as well as the terms of the broad consent to determine which future research uses remain within scope. This interpretation aligns with the Health and Human Services (HHS) Secretary's Advisory Committee on Human Research Protections (SACHRP) interpretation. Consequently, UCI is taking the same position as all UC's, Children's Hospital Orange County, Harvard, and Johns Hopkins and is not implementing Category 7, because UCI currently lacks a system-wide program for collecting broad consent.
8. **CFR 46.104(d)(8): Secondary research for which broad consent is required:** Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - i. **Broad consent** for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens **was obtained** in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);
 - ii. **Documentation of informed consent or waiver of documentation of consent was obtained** in accordance with 45 CFR 46.117;
 - iii. An **IRB conducts a limited IRB review** and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; **and**
 - iv. The investigator **does not include returning individual research results** to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual results.**Note: UCI will consider Category 8 on a case-by-case basis.** Researchers interested in Category 8 should contact HRP Staff for more information OR consider Expedited Review under Category 5.

- C. **Pre - 2018 Common Rule Exempt Categories:** For research that does not fall under the 2018 Common Rule (i.e., continuing studies approved before January 21, 2019 that are not receiving a new or renewal of a federal award (See Policy # 18)), research may be granted exempt status if all research activities involve procedures listed in one or more of the specific categories under **45 CFR 46.101(b)**:

1. **45 CFR 46.101(b)(1)**³: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - i. Research on regular and special education instructional strategies; or
 - ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. **45 CFR 46.101(b)(2)**⁴: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - i. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - ii. Any disclosure of the human subjects' responses outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. **45 CFR 46.101(b)(3)**: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 45 CFR 46.101(b)(2) if:
 - i. The human subjects are elected or appointed public officials or candidates for public office; or
 - ii. Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. **45 CFR 46.101(b)(4)**: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - a. To qualify for this exemption, data, documents, records, or specimens must have been collected before submission of the IRB application.

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The study procedures should not:

- Entail a significant deviation in time or effort from those educational practices already existent in the study site; or
- Involve an increase in the level of risk or discomfort beyond normal, routine educational practices.
- Note: The school or other institution grants written approval for the research to be conducted.

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If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the investigator(s) do not participate in the activities being observed. Audio/video recordings and photographs may be permissible in this category.

- b. Under this exemption, an investigator (with proper institutional authorization) may inspect private, identifiable records, but may only record information in a non-identifiable manner. The data must be permanently and completely de-linked at the time of extraction. A code may be used to organize data as it is collected. However, the code may not be a means of re-linking the data set to the original data source. Investigators are required to provide a data abstraction sheet to the IRB.
5. **45 CFR 46.101(b)(5):** Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

Public benefit or service programs; this exemption is for federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining (i) "public benefit or service programs:"

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act);
 - The research or demonstration project must be conducted pursuant to specific Federal statutory authority;
 - There must be no statutory requirements that the project be reviewed by an IRB; or
 - The project must not involve significant physical invasions or intrusions upon the privacy of participants.
- ii. Procedures for obtaining benefits or services under those programs;
- iii. Possible changes in or alternatives to those programs or procedures; or
- iv. Possible changes in methods or levels of payment for benefits or services under those programs.

Note: This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.

6. **45 CFR 46.101(b)(6) and 21 CFR 56.104(d):** Taste and food quality evaluation and consumer acceptance studies;
- a. If wholesome foods without additives are consumed; or
- b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- II. **2018 Common Rule Exempt Categories:** Exceptions to exempt research:
- A. These categories do not apply to research involving prisoners unless they are incidentally included.
 - B. Exempt categories 1-4 do not apply to FDA regulated research.
 - C. None of these exemption categories apply to research involving derivation and use of human embryonic stem cells or human embryonic germ cells, including somatic cell nuclear transplantation.
 - D. Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, does not qualify for exemption from IRB review.
 - E. Under FDA regulations at 21 CFR 56.104(c), the emergency use of test articles is exempt from IRB requirements. However, OHRP at 45 CFR 46 does not address emergency use of test articles. Emergency use constitutes emergency medical care, the patient is not considered to be a research subject; therefore, prior IRB review and approval is not required. Such emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity.
- III. **Pre - 2018 Common Rule Exempt Categories:** Exceptions to exempt research:
- A. These categories do not apply to research involving prisoners.
 - B. Exempt categories 1-4 do not apply to FDA regulated research.
 - C. None of these exemption categories apply to research involving derivation and use of human embryonic stem cells or human embryonic germ cells, including somatic cell nuclear transplantation.
 - D. Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, does not qualify for exemption from IRB review.
 - E. Under FDA regulations at 21 CFR 56.104(c), the emergency use of test articles is exempt from IRB requirements. However, OHRP at 45 CFR 46 does not address emergency use of test articles. Emergency use constitutes emergency medical care, the patient is not considered to be a research subject; therefore, prior IRB review and approval is not required. Such emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity.
- IV. All research conducted under exempt review is subject to all applicable UCI institutional and IRB policies and procedures.
- V. Exempt research activities are subject to the same subject protections and ethical standards as outlined in The Belmont Report.
- VI. Single IRB review requirements **do not apply** to exempt research.
- VII. The full Committee is advised of research proposals/activities that have been registered under the exempt review procedure. As a means of notifying the Committee and allowing for comments regarding a review conducted utilizing exempt review procedures, a report documenting registration of exempt research for the previous month is provided to the IRB Committee as a standing item on the IRB Committee meeting agenda.
- VIII. Modifications to Exempt protocols initially confirmed by the IRB are reviewed and approved by IRB Chairperson, designated IRB subcommittee, or HRP Staff Reviewer. If the amendment affects the status of the protocol review level, the designated HRP Staff Reviewer or IRB Chair will determine the appropriate review level (i.e., Expedited or full Committee review).

- IX. Use of the Exempt Self Determination Form by UROP undergraduate students are managed in accordance with the UROP program.

References:

OHRP 45 CFR 46

45 CFR 46.104(d)

45 CFR 46.101(b)

45 CFR 46.101(i)(footnote 1)

45 CFR 46.102(i)

45 CFR 46.201(b)

45 CFR 46.401(b)

21 CFR 56.104(c) and (d)

OHRP, *Exemption for Research and Demonstration Projects on Public Benefit and Service Programs*. <http://archive.hhs.gov/ohrp/humansubjects/guidance/exmpt-pb.htm>

OHRP, *Exempt Research and Research That May Undergo Expedited Review*, May 5, 1995.
<http://www.hhs.gov/ohrp/policy/hsdc95-02.html>

OHRP Compliance Activities: Common Findings and Guidance -7/10/2002

[NOT-OD-16-094](#)

45 CFR 46.114

Procedure Number: 12.A**Title: Procedure for IRB Review of Human Subjects Research – Exempt****Procedure:**

This procedure provides guidance in accordance with regulations to review and approve human subjects research in an exempt category.

I. Lead Researcher (LR) Responsibilities

- A. Where exempt self-determination is allowed, the Lead Researcher (including the UROP undergraduate student) (and Faculty Sponsor as applicable) complete the Exempt Self Determination Tool, available via the electronic IRB submission and management system.
- B. For exempt research that requires UCI IRB review, the IRB Application is completed in its entirety and electronically submitted to the HRP staff for processing. The Department Chair or the Organized Lead Unit Director logs into electronic IRB submission and management system to confirm their “approval” of the submission. (See IRB Policy 1.)
- C. The Consent form(s) is written using the template consent document, as applicable.
- D. When research requires UCI IRB review, the Investigator replies to all requests for revisions and/or clarifications requested by the HRP Staff Reviewer or IRB reviewer, when applicable.
- E. Once IRB confirmed as exempt, any proposed and necessary changes which require an amendment are submitted to the IRB via the electronic IRB submission and management system. (*See Policy # 17.) The Investigator must receive written IRB approval before implementing any changes to the research study.
- F. All unanticipated problems to participants or others or possible non- compliance are submitted to the IRB using the New Information Report in the electronic IRB submission and management system.

II. Reviewer Responsibilities

- A. The Reviewer reviews the IRB Application and validates or declines the researcher’s claim for review under the exempt category.
- B. The Reviewer reviews the proposed research, consents, and applicable documents to determine if the research meets the ethical standards of the Belmont Report. The Reviewer documents the exempt determination through the electronic IRB submission and management system.
- C. When the research involves interaction with subjects, a determination is made by the Reviewer whether some type of consent process is appropriate. The Reviewer documents the consent process in the electronic IRB submission and management system and the Exempt confirmation or registration letter. The Reviewer will ensure that the consent document provided to subjects contains such information as:
 - 1. a statement that the activity involves research;
 - 2. a description of the procedures;
 - 3. a statement that participation is voluntary;
 - 4. a statement that there are adequate provisions to protect the privacy and confidentiality of the subjects; and
 - 5. the name and contact information for the researcher.
- D. If the Reviewer disagrees with the proposed level of risk, the appropriate level of review is determined (i.e., Expedited). An IRB Chair will be consulted if the appropriate level of review is full Committee.

- E. If the Reviewer confirms the exemption, the Reviewer first completes a brief checklist in the IRB submission and management system and then a letter of Exempt Registration is generated.
- F. When revisions are requested prior to initial registration, the modified documents are re-reviewed and, if acceptable, exempt registration is granted.
- G. If proposed changes to an exempt study are submitted for review and approval, and the IRB requires a prospective review of such changes, the Reviewer will review and approve, as applicable.
- H. If needed, the IRB Chair or designated IRB subcommittee member is available to assist the Reviewer in determining if the study meets exemption criteria. If the Reviewer has a conflict of interest, another experienced Reviewer will conduct the review.
- I. HRP Staff Reviewers are delegated the authority to register IRB applications and approve amendments related to research activities deemed exempt from the federal regulations regarding the protection of human subjects under 45 CFR 46.101 (b). Exempt studies are accepted on a rolling basis and are administratively reviewed weekly by an HRP Staff Reviewer.
- J. Exempt Research receives a three-year registration with the UCI IRB. An abbreviated version of the renewal may be submitted to continue the research. The abbreviated renewal prompts the LR to confirm currently registered information about the research, as well as the status of enrollment. Finally, the LR can upload any relevant documents that the study team may want reviewed as part of the Exempt renewal.
- K. Delegation is provided in the HRP Staff Reviewer Delegation of Authority document maintained on the HRP WIKI page – and signed by the IRB Chairs for A, B, C, and Vice- Chair for Team D.
 - 1. An HRP Staff Reviewer is defined as follows:
 - a. **Tier 1:** Administrator or above, CIP certified and appointed as IRB members or alternate members. Exceptions are noted as applicable.
 - b. **Tier 2:** Analysts or above, CIP certified. Those without current CIP have been designated by an IRB Chair, Director or Assistant Director of Human Research Protections to have the appropriate experience to review minimal risk protocols. Exceptions are noted as applicable.
 - 2. An HRP Staff Reviewer may review and approve exempt protocols **with the following exceptions:**
 - a. Only an IRB Member or Tier 1 may review:
 - i. Protocols involving limited IRB review
 - ii. New or changes to waiver of HIPAA
 - iii. Involves California Information Practices Act
 - b. Only an IRB Member may review:
 - i. New of changes to disclosure of financial interest
 - ii. Potential noncompliance or unanticipated problem reported during last approval period
 - c. HRP Staff Reviewers may review and approve modifications related to exempt protocols in accordance with HRP Policy # 17

III. **Human Research Protections (HRP) Team Responsibilities**

- A. Conducts a pre-review to determine whether the application includes all information required and requests additional information, if needed, from the LR, to assist the Reviewer in making a determination.
- B. The HRP team will also review the proposed research to determine if it meets the ethical standards of the Belmont Report.
- C. Requests for information will be sent via to the LR via the electronic IRB submission and management system.
- D. When consultants to the IRB are utilized, obtain a signed Consultant's standards

document which includes a description of Disclosable Conflict of Interest and a statement of confidentiality.

- E. Assembles and prepares for distribution of review materials.
- F. Draft correspondence from the Reviewer and approval letters using the appropriate template which includes a citation to the specific permissible category or categories justifying the expedited review.
- G. New approvals, amendments and renewals are processed according to corresponding IRB policies and procedures.
- H. Appropriate database entries in the electronic IRB submission and management system are completed.
- I. Approved documents are processed.